K003797

DEC 1 5 2000

Special 510(k): ACE AIM® TTC Fusion Nail

510(k) Summary

Name of Sponsor:	**DePuy Orthopaedics, Inc.** 700 Orthopaedic Drive Warsaw, Indiana 46581-0988 Est. Reg. No. 1818910
510(k) Contact:	**Marcia J. Arentz** Senior Regulatory Associate Phone: (219) 371-4944 FAX: (219) 371-4940
Trade Name:	**ACE AIM® TTC Fusion Nail**
Common Name:	Intramedullary Fixation Rod
Classification:	**Class II** Device per 21 CFR 888.3020: Rod, Fixation, Intramedullary and Accessories
Device Product Code:	Code: **87HSB** Rod, Fixation, Intramedullary and Accessories.
Substantially Equivalent Device:	ACE AIM® Titanium Supracondylar Nail **K974781.**
Device Description :	The AIM TTC Fusion Nail is a straight, cannulated intramedullary nail available in diameters of 10 and 12 mm and lengths of 15, 20, and 25 cm. Holes in the nail allow for proximal and distal locking. The AIM TTC Fusion Nail, the end cap and the screws are all manufactured from Ti-6AL-4V alloy.
Intended use:	The AIM TTC Fusion Nail is intended for use in intramedullary fixation of supracondylar fractures of the femur, including those with severe comminution and intraarticular involvement, osteoporosis, non-unions, malunions, pathologic and fractures proximal to total knee arthroplasty or prosthesis. The AIM TTC Fusion Nail is also indicated for use in tibiotalocalcaneal fusions and treatment of trauma to the hindfoot and distal tibia.

510(k) Summary (continued)

Indications for use:

Indications include: Revision after failed ankle arthrodesis with subtalar involvement; Absent talus (Tibio Calcaneal Arthrodesis); Post traumatic/primary arthrosis involving both ankle and subtalar joints; A rheumatoid hindfoot; Avascular necrosis of the talus; Previously infected arthrosis, second degree; Failed total arthroplasty.

Substantial equivalence:

Based on conformance with the design control procedures similarities of design, commonly used materials, identical sterilization processes, and the same indications for use, DePuy believes that ACE AIM® TTC Fusion nail to be substantially equivalent to the FDA cleared ACE AIM® Titanium Supracondylar Nail.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2000

Ms. Marcia J. Arentz
Senior Regulatory Associate
DePuy Orthopedics, Inc.
P.O. Box 988
700 Orthopedic Drive
Warsaw, Indiana 46581-0988

Re: K003797
Trade Name: ACE AIM TTC Fusion Nail
Regulatory Class: II
Product Code: HSB
Dated: December 7, 2000
Received: December 8, 2000

Dear Ms. Arentz:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003797

Device Name: ACE AIM TTC Fusion Nail

Indications for Use:

The AIM TTC Fusion Nail is intended for use in intramedullary fixation of supracondylar fractures of the femur, including those with severe comminution and intraarticular involvement, osteoporosis, nonunions, malunions, pathologic and fractures proximal to total knee arthroplasty or prosthesis. The AIM TTC Fusion Nail is also indicated for use in tibiotalocalcaneal fusions and treatment of trauma to the hindfoot and distal tibia. Indications include: Revision after failed ankle arthrodesis with subtalar involvement; Absent talus (Tibio Calcaneal Arthrodesis); Post traumatic/primary arthrosis involving both ankle and subtalar joints; A rheumatoid hindfoot; Avascular necrosis of the talus; Previously infected arthrosis, second degree; Failed total arthroplasty.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use_____ OR Over-The-Counter Use
(Per 21 CFR 801.109)

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices

510(k) Number K003797